



# **Creatinine Accuracy Calibration Verification/Linearity Survey LN25**

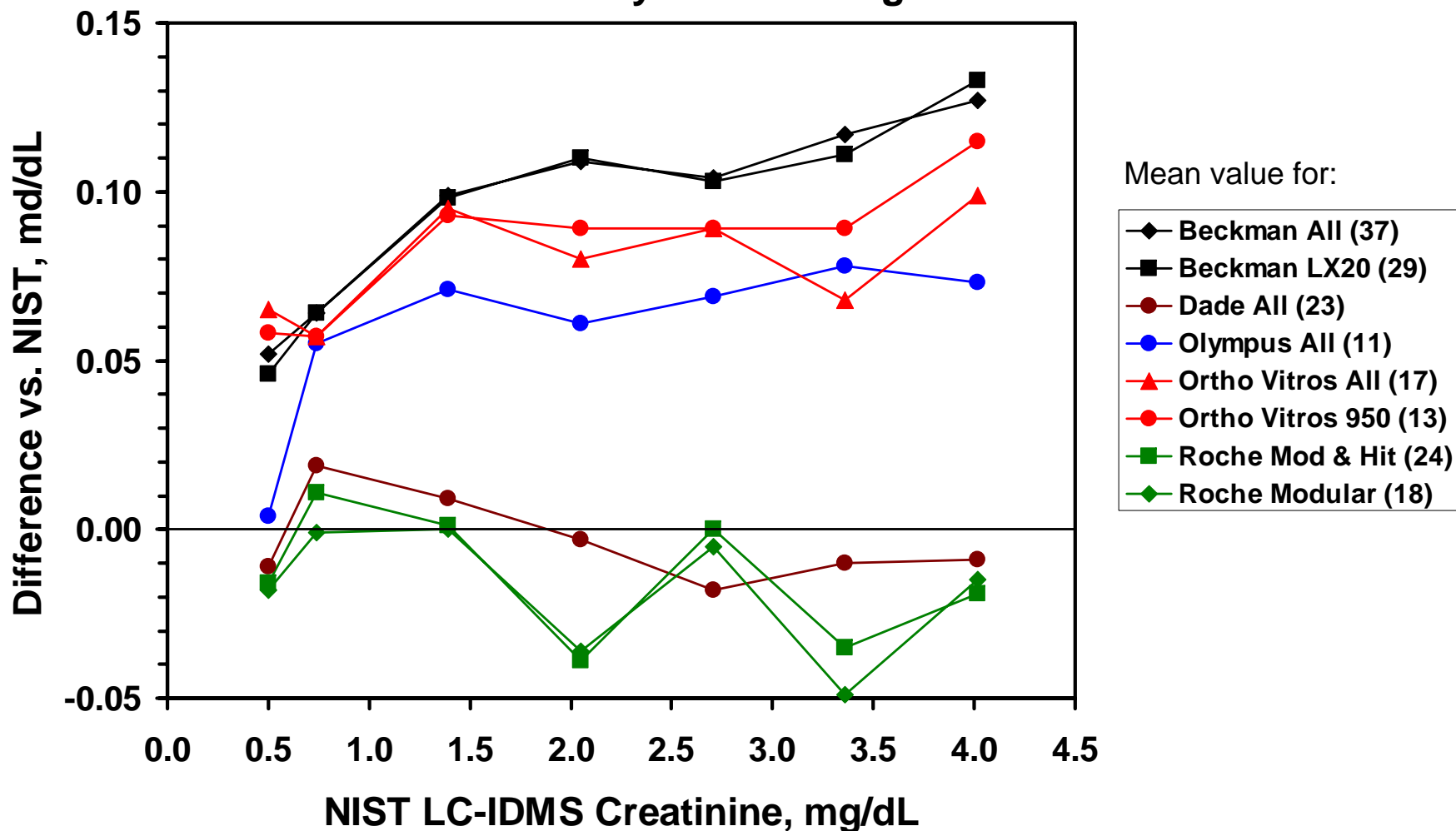
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- **Normal concentration pool prepared from fresh female off-the-clot serum (NCCLS C-37A)**
- **Normal pool was spiked with crystalline creatinine to prepare a high concentration sample**
- **Intermediate concentrations (LN03-06) were prepared by admixture of LN02 and LN07**
- **Low sample (LN01) was prepared by dilution of LN02 with phosphate buffered saline**
- **NIST value assigned normal (LN02) and high (LN07) samples by LC-IDMS; other concentrations by admixture and dilution ratios**



# Creatinine Accuracy Calibration Verification/Linearity Survey LN24

Results from May 2005 mailing





# Creatinine Accuracy Calibration Verification/Linearity Survey LN24

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Results from May 2005 mailing

Within method group CV, %

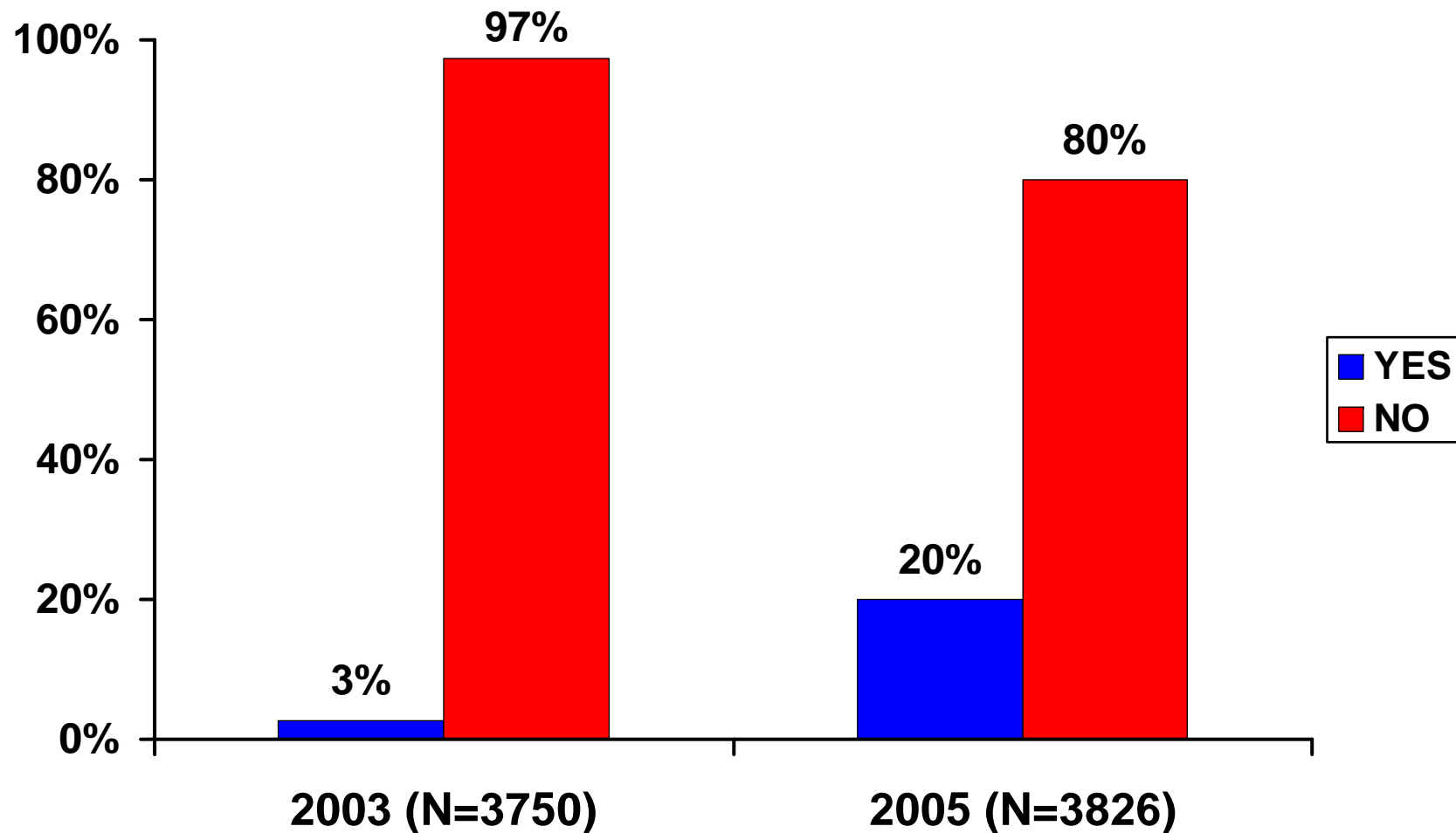
	N	LN24-01	LN24-02	LN24-03	LN24-04	LN24-05	LN24-06	LN24-07
<b>NIST value, mg/dL</b>		<b>0.501</b>	<b>0.739</b>	<b>1.394</b>	<b>2.049</b>	<b>2.705</b>	<b>3.360</b>	<b>4.015</b>
Beckman All	37	7.6	2.6	1.7	2.2	1	1.5	1.5
Beckman LX20	29	7.4	2.8	1.5	2.2	1	1.5	1.3
Dade All	23	4.1	7.6	0.8	3.1	2.2	2.1	1.7
Olympus All	11	3.7	2.1	4.3	1.2	2.1	2.4	2.4
Ortho Vitros All	17	7.4	2.5	1.4	1.9	0.6	2	1.4
Ortho Vitros 950	13	7.7	2.9	1.5	1.9	0.6	1.7	1.1
Roche Mod & Hit	24	11.1	8	1.5	0.9	2.4	2.3	2.2
Roche Mod	18	10.6	6.9	1.7	1	2.3	1.3	2.3



# Comprehensive Chemistry Survey

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## Number of labs reporting estimated GFR



# **SRM 967 Commutability Study**

**Purpose:** Establish commutability of SRM 967 for serum creatinine routine methods

**Materials:**

**☐ SRM 967**

- Level I – 0.80 mg/dL (70  $\mu$ mol/L)
- Level II – 4.0 mg/dL (355  $\mu$ mol/L)

**☐ CAP LN-24**

- LN24-01 (diluted)/0.501 mg/dL (44.3  $\mu$ mol/L)
- LN24-02 (base pool)/0.739 mg/dL (65.3  $\mu$ mol/L)\*
- LN24-07 (high pool)/4.015 mg/dL (354.9  $\mu$ mol/L)\*

**\* NIST value assigned**

# **SRM 967 Commutability Study - continued**

## **Materials:**

### **❑ Patient Samples**

- **20 samples collected from patients in the hypertension, diabetes, and transplant evaluation clinics at the University of Minnesota**
- **Concentration range 0.50-5.0 mg/dL (44-442 µmol/L)**
- **0.25 ml aliquots**
- **Routine methods – Beckman CX3\*, Roche (Jaffé)\*, Roche (enzymatic)\*, Vitros\*, Dade Dimension**

## **Analytical Scheme:**

- ❑ **Routine Methods – single batch analysis/ triplicate measurements**
- ❑ **Reference Method – duplicate measurements**

# **Timeline to introduce standardized creatinine and revised estimating equation**

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- **Revised equation for estimating GFR available in 2005**
  - **Further validation will occur for ethnic groups with possible further revision of equation**
- **SRM 967 with commutability validation available in late 2005/early 2006**
- **CDC reference measurement procedure (LC-IDMS) and serum panel available in 2006.**
- **Transition to new calibration of routine methods will require 6-24 months: complete late 2007-2008**
  - **Manufacturers have already recalibrated to IDMS**
  - **Manufacturers can make adjustments to existing lots in the field**
  - **Manufacturers will recalibrate with introduction of new lots**

# **Reference range recommendations?**

- 1. Manufacturer could provide magnitude of calibration change as a correction factor to the creatinine reference ranges**
- 2. Replace traditional creatinine reference ranges (do not report) with estimated GFR as a standardized clinical interpretation of creatinine**
- 3. Creatinine clearance reference range will be clinically different and should be discontinued?**



# **Next steps**

- 1. Deploy standardization program**
  - Target date to complete implementation of traceability and new estimating equation**
- 2. Deploy education program**
- 3. Coordination with IFCC and other professional organizations**
- 4. Coordination with pharmacy professional organizations**
- 5. Inform LIS/HIS computer software providers**
- 6. Develop guidelines for pediatric estimating equations**